Kuiper Certificering

Scheme Document for EC Type Examination

Contents

1. Introduction

kuiper certificering is accredited by RvA (Product Certification Body Registration Number C667) to perform EC type-examinations under the Machinery Directive 2006/42/EC for the scopes that it has been granted.

These scopes are published on the NANDO website or available from the accreditation body website.

2. The examination process

If the manufacturer's product(s) is being certificated for the first time, **kuiper certificering** will carry out an evaluation of the manufacturer's technical file(s), the equipment and a cross-examination of the technical file(s) and equipment to type.

Following a successful evaluation, review and certification decision making process, certification is granted for a 5-year period. If the manufacturer continues to place the equipment on the market, he shall request renewal of the certificate for a further 5-years.

3. The application process

Prior to the start of the evaluation process, the applicant shall provide a technical file to allow **kuiper certificering** to assess the scope of certification and its competence to complete the work.

Each application will be handled in a non-discriminatory manner and **kuiper certificering** is committed to making its services accessible to all applicants whose activities fall within its scope of certification. Access to the certification process is not conditional upon the size of the applicant or membership of any association or group, nor will certification be conditional upon the number of certifications already issued, or any other undue factor.

Applications shall be submitted in writing. As part of this application the applicant must provide the manufacturer's legal name and address (and that of its Authorised Representative if applicable) and declare that the product has not been submitted for evaluation to another Notified Body. He shall submit the technical file as part of the application process.

kuiper certificering will decide to accept or decline the application. If the application is declined, the applicant will be informed in writing stating reasons. The application will be declined if the product is not within **kuiper certificering's** certification, or competent resources are not available to conduct the examination work.

4. Certification agreement

Before the evaluation can proceed, the manufacturer shall sign a Certification Agreement with **kuiper certificering**. This agreement covers all certification activities by **kuiper certificering** for the manufacturer.

5. Contract review

kuiper certificering will carry out a contract review during the application process. This review will address scope, compliance, availability of competent resources and impartiality.

6. The evaluation process

The evaluation process involves a review of the technical file for the equipment and an on-site evaluation of the equipment, or a sample or samples of the equipment. The evaluation includes a cross-check of the equipment against its technical file.

The client will be required to place at the disposal of **kuiper certificering** a sample of the type. **kuiper certificering** may ask for further samples if the test programme so requires.

6.1. Communication during the examination

During the examination of the equipment, the examiner may communicate with the client on the progress of the examination and any concerns that may arise. If the examination objectives are unachievable or if an immediate risk to safety arises, the examiner will report this to the client and take appropriate action. Actions may include examination modifications, changes to scope or termination of the examination.

6.2. Examination planning

Upon completion of the application process, **kuiper certificering** will arrange the evaluation and will submit an examination plan.

The examination plan will identify which elements of the machinery have been designed in accordance with the relevant provisions of harmonised standards, and those elements whose design is based on compliance with the EHSRs directly.

In determining the time required for the examination we will consider, among other things: the number of products, location of the products, availability of samples, scope and complexity of the products and any associated risks.

As part of the examination planning, **kuiper certificering** will determine compliance of any measuring equipment with associated calibration requirements.

6.3. Technical file review

kuiper certificering shall carry out a review of the technical file. The duration will depend on the size and complexity of the equipment, the number of models and ranges covered and the applicability of C-type harmonised standards.

Where the client is engaged in series manufacture, **kuiper certificering** will require evidence that the manufacturer has in place a system for ensuring product reproducibility.

The initial technical file review shall be completed before commencement of on-site evaluation, and any non-conformances will be submitted to the client.

6.4. On-site testing and inspection of the equipment

The client will propose a location or locations for the on-site evaluation to be conducted, which will be agreed with **kuiper certificering.** The client has the responsibility for providing facilities, equipment, tools and trained operators for any witnessed tests. The duration will depend on the size and complexity of the equipment, the number of models and ranges covered and the applicability of C-type harmonised standards.

The costs of any damage to or loss of equipment under test, materials or test equipment shall be borne by the manufacturer.

Any work on live electrical systems shall be carried out by the mnaufacturer’s personnel.

The on-site evaluation visit will be undertaken in accordance with the examination plan. The examination team may consist of one or more examiners and may be accompanied by members of accreditation bodies. The purpose of the on-site evaluation is to assess the equipment for compliance and cross-check the equipment with the technical file.

The on-site evaluation of the equipment will comprise:

- An opening meeting to introduce the examiner, explain the examination process, make certain that all required resources are available, and ascertain that the examination can proceed as planned,
- Evaluation of the equipment with the aim of establishing compliance with the identified requirements,
- A closing meeting to explain the findings, and the further steps of the process.

During the opening meeting the examiner will check that

- The machine is operational,
- The inspection can be carried out in a safe environment,
- There are adequate facilities for the examination team.

The inspection will consist of:

- Validation of hazard identification,
- Review of the equipment against the Risk Assessment,
- Checking safety measures taken and residual risks,
- Functional testing of the safety devices,
- Review of the equipment against a C-type harmonised standard and/or the EHSRs,
- Tests and measurements necessary to verify that standards have been applied and EHSRs have been met,
- Review of supporting documents (detailed drawings, calculations, notes, test reports),
- Checking labels,
- Checking manuals.

During the closing meeting the findings of the examination will be discussed and a period for correcting any non-conformances will be agreed. A period of 90 days or so will be agreed.

6.5. Reporting

The examiner will prepare an examination report detailing observations, non-conformances and areas of compliance.

6.6. Examination findings

If non-conformances are identified during the examination these will be discussed with the client during the closing meeting.

Non-conformances will be issued in the examination report. For each non-conformance the client must analyse the root cause and describe the corrective actions required to resolve the non-conformance.

All non-conformances must be closed out to the satisfaction of the examiner who will then make a certification recommendation.

Failure to resolve any non-conformances may result in a refusal to issue certification or the reduction, suspension or withdrawal of certification already issued.

7. The review process

kuiper certificering will carry out a review of the examination to ensure it has been effective and that any non-conformances have been resolved satisfactorily. The reviewer will not be the same person as the examiner.

8. Certification decision

Review and Certification Decision making may be carried out by the same person. The recommendations of the examiner and the reviewer are considered by the **kuiper certificering** certification decision maker (CDM) responsible for taking certification decisions. If deemed appropriate, the CDM will confirm the recommendations. Where certification is granted, a certificate will be issued to the client covering the equipment, sample machine and locations (if applicable) showing the initial certification date and the expiry date. This certificate is valid for 5 years, and is subject to the company

continuing to meet the requirements of the Machinery Directive and the contractual requirements in **kuiper certificering** Terms and Conditions, and the Certification Agreement.

9. Special examinations – extra visits

kuiper certificering may need to perform extra visits in the case of concerns around compliance. The customer will be informed of these visits in advance and will be charged. Extra visits that are deemed necessary by **kuiper certificering** are a prerequisite to continued certification.

A special examination at short notice may be required as part of the investigation into any complaint. Special examinations may also be required as part of the follow up process for suspensions, either to confirm suspension conditions are being followed or as part of the reinstatement process.

10. Ongoing responsibilities

10.1. Retention of documentation

The client and **kuiper certificering** shall retain a copy of the certificate, the technical file and all other relevant documents for a period of 15 years from the date of issue of the certificate.

10.2. Notification of changes and extensions to the scope of certification

The manufacturer has the ongoing responsibility of ensuring that the certified equipment meets the corresponding state of the art.

kuiper certificering shall inform the client of changes that will have an impact on the validity of certificates. These include, for example, changes relating to:

- The withdrawal and introduction of harmonised standards,
- New and amended directives.

The manufacturer shall inform **kuiper certificering** without delay of any matters that may affect the continued validity of the certificate. These include, for example, changes relating to:

- The legal, commercial, organizational status or ownership,
- Organization and management (e.g., key managerial, decision-making or technical staff),
- Contact address and sites,
- Modifications to equipment,
- Major changes to the management system and processes,
- Additions to ranges.

Any modifications to machinery that affect safety, shall be submitted by means of an application for modification to **kuiper certificering.**

kuiper certificering will adapt the scope of certification to reflect these changes where continued compliance is demonstrated. If the scope of certification is unaffected by the change, **kuiper certificering** will take the decision to maintain the current certification, which will be communicated to the client.

Where a client persistently or seriously fails to meet the certification requirements for parts of the scope of certification these parts will be excluded from the certification and the scope of certification will be reduced. Any such reduction shall be in line with the requirements of the standard used for certification.

Should **kuiper certificering** receive any complaints about products that have been certificated, these complaints will be investigated.

11. Renewal and withdrawal on expiry of certification

The manufacturer shall request from **kuiper certificering** the review of the validity of the EC type-examination certificate every five years.

13 months prior to the end of the 5-year certification cycle, **kuiper certificering** will contact the client regarding renewal of the certification. A programme of work will be drawn up and a quotation offered to the client. The renewal process involves evaluation, review and certification.

If **kuiper certificering** finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.

If the client chooses not to apply for renewal of a certificate, or the renewal process has not been completed, the certificate will be withdrawn on the date of expiry. The notification of withdrawal may be issued in advance of the date of expiry. After the certificate is withdrawn, no reference may be made to the **kuiper certificering** type-examination certificate on the Declaration of Conformity for the product(s).

kuiper certificering will inform its notifying authority of certificates issued and withdrawn due to expiry.

12. Refusal, suspension or forced withdrawal of certification

If the client does not comply with the requirements of the certification scheme, the Certification Agreement or Terms and Conditions, **kuiper certificering** reserves the right to refuse, suspend or withdraw the certification.

Reasons for refusal, suspension or forced withdrawal of certification may include the following:

- The equipment has persistently or seriously failed to meet the certification requirements,
- Non-conformances have not been satisfactorily actioned, within the designated time limit,
- A case of misuse of a certificate is not corrected by suitable retractions or other appropriate remedial measures,
- There has been any other contravention of the **kuiper certificering** Terms and Conditions, Certification Agreement or this scheme,
- Reassessment visits do not take place within the prescribed timeframe.

The client shall not claim certification for any product covered by a suspended or withdrawn certificate.

The client will be notified in writing of the suspension of a certificate. **kuiper certificering** will indicate under which conditions the suspension will be removed.

Within the suspension period, an investigation will be carried out to determine whether the indicated conditions for restoring the certificate have been fulfilled. On fulfillment of these conditions, the suspension shall be lifted, and the client will be notified of the certificate restoration. If the conditions are not fulfilled, the certificate shall be withdrawn.

All costs incurred by **kuiper certificering** in suspending and restoring a certificate will be charged to the client.

In cases of forced withdrawal, no reimbursement of examination fees shall be given.

kuiper certificering will inform its Notifying Authority of certificates refused, restricted, suspended or withdrawn.

Where certification is not granted, **kuiper certificering** will notify the client in writing, detailing the reason(s) why certification has been refused. **kuiper certificering** will inform the notifying authority and all other applicable Notified Bodies of the refusal to certificate.

13. Voluntary withdrawal of certification

If the client wishes to voluntarily elect for **kuiper certificering** to withdraw a certificate**,** the client must do so in writing. The client must state the date by which it wants the certificate to be withdrawn, which must be a date in the future. No reimbursement of examination fees shall be given, and **kuiper certificering** will inform the notifying authority. Upon withdrawal of the certificate, the client shall not claim certification for any product covered by the withdrawn certificate.

14. Confidentiality

To enable **kuiper certificering** to do its job effectively it must have knowledge and information about its client's organisation. **kuiper certificering** is aware of the need for confidentiality, and all contracts with clients are subject to this requirement. All **kuiper certificering** employees and subcontractors are bound by signed confidentiality agreements.

The Commission, the Member States and other notified bodies may, on request, obtain a copy of the EC type-examination certificates from **kuiper certificering**. On reasoned request, the Commission, the Member States, and Market Surveillance Authorities may obtain a copy of the technical file and the results of the examinations carried out by **kuiper certificering**.

15. Impartiality

kuiper certificering understands the importance of impartiality and is committed to carrying out its certification activities in an impartial manner. **kuiper certificering** has a process to manage conflicts of interest and is committed to ensuring that the objectivity of its certification activities is maintained. **kuiper certificering** has appointed an Impartiality Board that audits the company on a regular basis on issues of impartiality.

16. Appeals

The client has the right to appeal against certification decisions. The client must follow the **kuiper certificering** appeals process which is outlined in a separate document which will be provided upon request.

17. Complaints

If the client has cause to complain regarding the conduct of **kuiper certificering** or its employees, the complaint must be made in writing, within 3 months of the cause of the complaint, and addressed to the **kuiper certificering** Managing Director. All complaints are logged, investigated and monitored. It is our intention to deal with complaints promptly and appropriately. We will keep the client informed of the progress and status of the complaint. The final result of the complaint will be communicated in writing.

18. Review of the certification scheme

kuiper certificering reserves the right to review, revise, amend or replace the requirements for certification, and introduce new requirements from time to time reflecting the changing needs of the business or changes in requirements in accreditation or certification standards.